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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/583,046  | 06/15/2006  | Keiji Kubo           | 8279.1128USWO       | 7165             |
| 52835 7590 12/20/2007<br>HAMRE, SCHUMANN, MUELLER & LARSON, P.C.<br>P.O. BOX 2902 |             |                      | EXAMINER            |                  |
|   |             |                      | CHU, YON            | CHU, YONG LIANG  |
| MINNEAPOLIS, MN 55402-0902  |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1626                |                  |
|   |             |                      |                     |                  |
|   |             |                      | MAIL DATE           | DELIVERY MODE    |
|   |             |                      | 12/20/2007          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  | Application No.  | Applicant(s)   |  |  |  |
|--|--|--|--|--|--|
|  | 10/583,046   | KUBO ET AL.  |  |  |  |
| Office Action Summary  | Examiner   | Art Unit   |  |  |  |
|  | Yong Chu   | 1626   |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).   | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be timediately and will expire SIX (6) MONTHS from a cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |
| Status   |  |  |  |  |  |
| <ul> <li>1) Responsive to communication(s) filed on 15 June 2006.</li> <li>2a) This action is FINAL.</li> <li>2b) This action is non-final.</li> <li>3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.</li> </ul>   |  |  |  |  |  |
| Disposition of Claims  |  |  |  |  |  |
| 4) Claim(s) 1-30 is/are pending in the application.  4a) Of the above claim(s) is/are withdray  5) Claim(s) is/are allowed.  6) Claim(s) is/are rejected.  7) Claim(s) is/are objected to.  8) Claim(s) 1-30 are subject to restriction and/or example.  | vn from consideration.   |  |  |  |  |
| ·· _   | •  |  |  |  |  |
| <ul> <li>9) The specification is objected to by the Examiner.</li> <li>10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.</li> <li>Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</li> </ul>  |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |  |  |  |  |  |
| Priority under 35 U.S.C. § 119   |  |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul> |  |  |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date   | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:   | ate  |  |  |  |

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## DETAILED ACTION

Claims 1-30 are currently pending in the instant application and are subject to the following lack of unity requirement.

## Election/Restrictions

Restriction is required under 35 U.S.C. 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Claims 1-30 are drawn to more than one inventive concept (as defined in PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Due to lack of core structure and the numerous and widely divergent variables in

the compound of formula (I)

Cy—N—V—W—X—Y—N A — Z—B

, for example C<sub>y</sub>, R<sup>1</sup>, V, W,

X, Y, Z, A, and B, the general formula I contains various distinct special technical

features, and therefore the inventions are lack of unity. The only constant element in

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the formula (I) is "N". It is not acceptable for search such diversified chemical formula. For this reason, a restriction requirement is required. Since a precise listing of inventive groups cannot be made, the following restriction requirement is required, and will be subject to for further restriction requirement, if necessary.

Group I: Claims 1-23, and 30 are drawn to a compound of formula (I), and a pharmaceutical composition comprising the said compound according to claim 1.

Group II: Claims 24-26 are drawn to a method of inhibiting blood coagulation in mammal which comprises administering an effective amount of the compound according to claim 1 or a prodrug thereof.

Group III: Claims 27-29 are drawn to use of the compound according to claim 1 for the manufacture of a medicine for inhibiting blood coagulating.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. The elected group is subject to further restriction.

Again, this list is not exhaustive as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore,

Applicant also needs to elect a single compound as the elected species for initial search purpose.

The claims herein lack unity of invention under PCT rule 13.1 and 13.2 since, under 37 CFR 1.475(a) the compounds defined in the claims lack a significant structural element qualifying as the special technical feature evidenced by formula I' with numerous and widely divergent variables in the compound of formula (I').

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Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

Additionally, the vastness of the claimed subject matter, and the complications in understanding the claimed subject matter imposes a serious burden on any examination of the claimed subject matter.

## Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed Yong Chu whose telephone number 571-272-5759. The examiner can normally be reached on 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. M<sup>©</sup>Kane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free) KAMALA OFFICE PAID.

Yong Chu, Ph.D. Patent Examiner Art Unit 1626

Kamal Saeed, Ph.D. Primary Patent Examiner

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